IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ROCIO HERRERA-NEVAREZ, by Thomas E. Springer, Trustee of the bankruptcy estate of Rocio Herrera-Nevarez,	)	
Plaintiff,	)	
vs.	)	**Case No. 17 C 3930 (formerly Case No. 12 C 2404)**
ETHICON, INC. and JOHNSON & JOHNSON,	)	
Defendants.	)	

ORDER ON MOTIONS IN LIMINE

This case is set for trial on August 15, 2017. The Court rules as follows on the parties' motions *in limine*. In some instances, the Court adopts its rulings as described orally at the final pretrial conference held on August 2, 2017.

The Court expects and directs counsel to advise witnesses in advance of their testimony of its rulings on these motions so that they are not violated. The Court also directs counsel to promptly conform their deposition designations to the Court's rulings.

Finally, the Court notes that a party that has succeeded in excluding evidence may, of course, open the door to its admissibility. If an opposing party believes this has occurred, it must raise the issue outside the jury's presence and seek permission before introducing evidence the Court has excluded.

A. Plaintiff's motions

1. References to bankruptcy and bankruptcy trustee

For the reasons described at the final pretrial conference, any references to plaintiff's bankruptcy and the bankruptcy trustee are barred. All counsel, parties, and witnesses are to refer to the plaintiff as Rocio Herrera-Nevarez.

2. "Unrelated medical conditions"

Reference to the following medical conditions is barred as irrelevant and unfairly prejudicial and confusing in a way that far outweighs the probative value of such evidence:

- plaintiff's use of an intrauterine device (and any references to IUDs are to be redacted from any medical records displayed or introduced at trial);
- ovarian cysts;
- hemolytic anemia;
- use of Rituxin and references to chemotherapy;
- endometrial thickening;
- constipation and medication for it (unless defendants first demonstrate, outside the jury's presence, a proper foundation establishing the relevance and probative value of such evidence).

The Court declines to bar reference to diabetes, obesity; smoking; yeast infections; vaginal infections; and urinary tract infections. Defendants have shown a sufficient foundation for admission of this evidence as relevant. Plaintiff's arguments may affect the weight to be given the evidence, but they do not affect its admissibility.

3. Testimony by Dr. Leung

Evidence that Dr. Leung diagnosed plaintiff with and treated her for diabetes is relevant and not unfairly prejudicial or confusing, even though Dr. Leung did not treat plaintiff until 2014. Defendants have a sufficient basis to advance a theory that plaintiff's injuries result from her diabetes, and Dr. Leung's testimony is admissible to establish the predicate, namely that plaintiff suffers from this condition.

The Court is unpersuaded, however, that Dr. Leung's testimony is relevant or admissible except to the extent necessary to lay the foundation for testimony regarding diabetes as a possible causal factor. The Court encourages the parties to limit the designations from Dr. Leung's deposition accordingly and reserves the right to do so itself.

4. AUGS / SUFU position statement

The AUGS / SUFU position statement regarding "mesh midurethral slings for stress urinary incontinence," *see* Pl.'s Mot., Ex. A, is relevant, and if the appropriate foundation is laid, its contents likely are admissible as a learned treatise under Federal Rule of Evidence 803(18)—though, as that rule provides, the document itself will not be admitted as evidence. Plaintiff's contentions regarding the circumstances under which the position statement was developed and released go to the weight to be given the position statement and do not undercut its admissibility. The same is true of plaintiff's contention that the position statement covers products other than the TVT-O product involved in this case. The Court notes, however, that for this reason and because the position statement was issued in January 2014, the use of the position statement by defendants may open the door to other evidence with one or both of those same

characteristics (i.e., concerning other products and at dates post-dating the use of the product with plaintiff).

5. The product or similar products are still on the market

Defendants argue that the fact that the TVT-O and similar devices are "still on the market . . . [and] are the overwhelming choice of surgeons who treat stress urinary incontinence" is strong evidence against plaintiffs' design defect claim. Defs.' Resp. to Pl.'s Mots. *in Limine* at 8. They also argue that if this evidence does not come in, the jury will believe the product has been taken off the market, and this will unfairly prejudice defendants. *Id.* The Court is persuaded that evidence the product is still on the market is relevant and admissible, for the reasons defendants contend. But defendants cannot expect that their introduction of this evidence for the purposes cited is a consequence-free decision in terms of admissibility of countervailing evidence offered by plaintiff.

6. Data / studies / literature on products other than TVT-O

Both sides want to use evidence regarding mesh products other than TVT-O but bar their opponent from doing so. *Compare* Pl.'s Mot. *In Limine* 6 *with* Defs.' Mot. *In Limine* 18. The Court is unpersuaded that there is any reasonable way to reconcile each side's opposing arguments on these two motions. The Court is also unpersuaded that a complete ban on such evidence is called for under Federal Rules of Evidence 402 or 403, or otherwise. It is certainly conceivable that particular items of evidence along these lines may be irrelevant or excludable under Rule 403, but that will have to be addressed on an item-by-item basis, and it will be up to the parties to make appropriate objections during the trial when appropriate.

7. Termination of plaintiff's employment

Evidence regarding the circumstances of the termination of plaintiff's employment is irrelevant. Even were this not the case, its probative value—supposedly regarding plaintiff's credibility—is so minuscule that it is far outweighed by the danger for jury confusion and the large detour from the issues in the case that its admission would entail. The Court excludes this evidence.

8. Reference to TVT-O as the "gold standard" of treatment

The Court is unpersuaded that testimony to the effect that TVT-O represents the gold standard of treatment for stress urinary incontinence (SUI) is irrelevant or that it should be excluded under Federal Rule of Evidence 403. The Court agrees with defendants that such evidence is relevant and admissible on the question of whether the TVT-O is unreasonably dangerous.

9 & 10. Statements about counsel, advertising for lawsuits, hiring of counsel, and counsel's fees

Evidence or argument about opposing counsel, advertising by lawyers for TVT-related plaintiffs, the timing and circumstances of plaintiff's retention of counsel, or fees that counsel may earn is not likely to make any fact in issue more or less likely and is thus inappropriate and inadmissible. The Court grants these motions.

11. Negligence, contributory / comparative fault by plaintiff, failure to mitigate

There is no defense, and certainly no viable defense, of contributory negligence in this case, so evidence or argument to the effect that plaintiff is at fault or responsible for her injuries is inadmissible and is barred. As indicated in the ruling on plaintiff's

motion *in limine* 2, this does not preclude defendants from introducing otherwise admissible evidence regarding plaintiff's smoking, diabetes, or obesity. In addition, defendants conceded at the final pretrial conference that evidence regarding the fact that plaintiff did not undergo further surgery to remove the TVT-O is inadmissible.

12. Widespread use of pelvic mesh

As with the motion regarding reference to TVT-O as the "gold standard" of treatment, the Court is unpersuaded that evidence regarding widespread use of pelvic mesh is irrelevant or that it is inadmissible under Federal Rule of Evidence 403. Again, however, defendants cannot reasonably expect that their introduction of such evidence is a consequence-free choice on their part.

13. Defendants' unrelated "good acts" / reputation

This evidence is excluded as discussed at the final pretrial conference.

14. Defendants' "emotional feeling toward plaintiff"

The Court will not bar defense counsel from expressing during argument that defendants have sympathy for plaintiff, but that is the extent of it. In other words, defendants may not elicit *testimony* along these lines from witnesses. In addition, if defense counsel attempt to overdo it during opening statement or closing argument, the Court will intervene and will give whatever curative instructions are appropriate.

15. Certain arguments regarding damages

Argument or evidence that plaintiff is requesting more damages than she thinks the jury will award or that she actually thinks she is entitled to, or regarding the fact that counsel may get part of any award, is irrelevant and unfairly prejudicial. The Court grants this motion.

B. Defendants' motions

For defendants' motions, the Court uses the same numbering system defendants used in their supporting memorandum (dkt. no. 224).

3. Post-implant revisions to device or warnings

In 2015, changes were made to warnings issued along with the TVT-O. Defendants say that some of these were requested by Canadian regulatory authorities and others were made by Ethicon on its own initiative and that for purposes of U.S. disclosures, the changes were "purely voluntary." Defs.' Mots. *In Limine* at 3. Defendants move to bar evidence of the label changes under Federal Rule of Evidence 407, which states that

> [w]hen measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove:
>
> - negligence;
> - culpable conduct;
> - a defect in a product or its design; or
> - a need for a warning or instruction.
>
> But the court may admit this evidence for another purpose, such as impeachment or—if disputed—proving ownership, control, or the feasibility of precautionary measures.

Defendants rely primarily on *Chlopek v. Fed. Ins. Co.*, 499 F.3d 692 (7th Cir. 2007). In that case, the plaintiff challenged the trial court's exclusion of evidence that defendant changed the label on a medical device some time after the plaintiff's injury. The plaintiff argued that because the defendant contended that it had made the change voluntarily and not due to safety concerns, it was not a remedial measure. The court rejected this argument, saying that under the text of Rule 407, the party's motive for making the change "is irrelevant. All the rule requires is that the measure would have made the

injury or harm less likely to occur." *Id.* at 700 (internal quotation marks omitted).

In this case as in *Chlopek*, plaintiff argues that the labeling revisions are not "remedial conduct" given defendants' statements that the labeling was at all times adequate to apprise users of risks and that the change was not made for safety-related or other remedial reasons. That argument is foreclosed by *Chlopek*; it is the exact argument made and rejected in that case.

Plaintiff next argues that the labeling change is relevant to show notice with respect to the TVT-O device. But she has not explained—nor can the Court see—how notice in 2015 has anything to do with liability in a case that involves a device implanted in 2005.

Plaintiff's next argument is that the labeling revisions are relevant to show causation. At the final pretrial conference, defendants' counsel argued that Rule 407 forecloses use of subsequent measures to prove causation. In fact, though, the text of the rule does not support that argument. It bars evidence of subsequent measures to show negligence, culpable conduct, a product defect, or the need for a warning; it says nothing about causation, an element that is logically distinct from each of the listed issues. And when the Seventh Circuit dealt with a similar argument in *Chlopek*, it did not address it as an issue under Rule 407 but rather as an issue of relevance and unfair prejudice. Here is the court's discussion:

> The plaintiffs get no further by arguing that the evidence of the changed warning nevertheless was admissible because it was relevant to causation. The fact of a new warning does not tend to prove that the absence of an adequate warning caused [the plaintiff's] injury; rather, it is relevant to whether continuous use of the product can cause injury. However, [the defendant] never argued that its product could not cause an injury like [plaintiff's]. its position was that with proper use (including heeding the existing warnings) on appropriate candidates the product was

> safe. In any event, the district court found that evidence of a changed warning label was excludable for the additional reason that it would be unfairly prejudicial, *see* Fed. R. Evid. 403, and this determination was not an abuse of discretion.

Chlopek, 499 F.3d at 700.

Had the court in *Chlopek* believed that use of subsequent measures to show causation was barred by the first sentence of Rule 407, it would have been easy for the court to say so. The court's analysis of the issue under different rules (402 and 403) is a pretty strong indication that causation—like ownership, control, or the feasibility of precautionary measures—is one of the alternative purposes that in appropriate circumstances permits introduction of subsequent measures. And indeed there is authority to this effect, though the conclusion is not unanimous. *See Brazos River Auth. v. GE Ionics, Inc.*, 469 F.3d 416, 429 (5th Cir. 2006) ("[S]ubsequent remedial measures can be introduced on the issue of causation if that is in controversy."); *Wetherill v. Univ. of Chi.*, 565 F. Supp. 1553, 1557-58 (N.D. Ill. 1983); *contra, Werner v. Upjohn Co.*, 628 F.2d 848, 859 (4th Cir. 1980) ("[T]he policy behind Rule 407 does not allow for a new exception to prove causation . . . on the facts of this case."). The Court finds *Brazos River Authority* and *Wetherill* persuasive. In this regard, the Court notes, among other things, that the last sentence in Rule 407—the one with the "exceptions," as the court called them in *Werner*—is an expressly non-exclusive list.

But that does not mean that subsequent measures are *automatically* admissible if used to show causation. The last sentence in Rule 407, the part of the rule under which evidence may be admissible for this purpose, has a threshold requirement that the particular issue must be "disputed." And in this case, defendants say that they are not contesting general causation, that is, the proposition that the TVT-O *can* cause

injuries of the types described in the warnings. Rather, they are contesting specific causation, that is, the proposition that the TVT-O caused plaintiff's own injuries. If that is so, then the case is no different from *Chlopek* on this point, as the court in that case upheld the exclusion of the labeling change on the ground that it was relevant only on general causation, a point that was not contested. *See Chlopek*, 499 F.3d at 700. Thus if, as defendants contend, there is no dispute or contest (via evidence or argument) about whether the TVT-O *can* cause injuries of the type described in the enhanced warnings, evidence of the change remains inadmissible under Rule 407 to show causation.

Plaintiff's final argument, however, has merit. She argues that if defendants are permitted to offer evidence that the product is still on the market and being used in tens of thousands of patients even today (and post-2015), this opens the door to evidence regarding the labeling change. The Court agrees. The Court agreed with defendants' argument, made in opposition to plaintiff's motion *in limine* 5, that it would be unfair to leave the jury with the impression that the product has been taken off the market. *See* Defs.' Resp. to Pl.'s Motion *In Limine* at 8. The flip side of this point, however, is that it would be unfairly prejudicial to allow defendants to introduce ongoing, widespread use of the TVT-O (or similar devices) but leave the jury with the false impression that this is occurring under the same labeling and warnings that were in place when the product was used in plaintiff. Defendants' argument or evidence regarding ongoing use of the product and the fact that it is still on the market opens the door to introduction of the 2015 labeling change.

4. Demonstrations / handling of product

As discussed at the final pretrial conference, an exemplar of the TVT-O may be used as a demonstrative exhibit at trial and may be displayed to (and passed around by) the jury in its container. No witness or attorney may conduct stretching or similar demonstrations with the device. And because the device will be a demonstrative exhibit, it will not go to the jury during deliberations. Either party may, of course, introduce photographs of the device into evidence.

6. Other lawsuits involving TVT-O or other TVT devices

Evidence about other lawsuits about the TVT-O or other TVT devices in which defendants have suffered an adverse verdict is unfairly prejudicial and inadmissible under Federal Rule of Evidence 403. The same is true with regard to evidence of the number of other *lawsuits* concerning the device.

It is equally inappropriate, however, for defendants to paint an unfairly misleading picture for the jury. As discussed earlier, defendants contend that the safety and efficacy of these devices is shown by their widespread and ongoing use and that they represent the "gold standard" for treatment of SUI, and they intend to introduce evidence and argument to that effect. Were this evidence to come in without any reference to reports of injury—which may include lawsuits—there would be a risk of misleading the jury. It is unclear to the Court at this point, however, whether this is a significant risk. The Court needs to have further discussion with counsel regarding exactly what evidence, aside from lawsuits, will be introduced regarding adverse reports and complaints about the TVT-O and similar devices, and whether there is a reasonable and fair way to include lawsuits—without referring to them as such—among the

evidence regarding adverse reports and complaints. The Court intends to have a further discussion with counsel later this week, prior to trial, regarding this point. Final ruling on defendants' motion *in limine* 6 is held in abeyance until that time.

9. Medical device reports / adverse event reports

The Court bars introduction of "medical device reports" whose admission is barred by 21 U.S.C. § 360i(b)(3), specifically, those made by hospitals and by physicians who are not required to report. The cited statute says that such reports may not be introduced in evidence. *See* Defs.' Mots. *In Limine* at 7. That aside, however, adverse event reports for injuries similar to those claimed by plaintiff predating her injury are admissible to show notice (a non-hearsay use).[1] Defendants' argument to the contrary goes only to the weight to be given this evidence, not its admissibility.

The Court defers ruling on post-injury adverse event reports, for the reasons discussed with regard to defendants' motion *in limine* 6.

11. Luscombe marketing presentation

As discussed at the final pretrial conference, the Luscombe PowerPoint presentation has, at most, very limited probative value, and its admission would unfairly prejudice defendants. It is excluded.

12. Complications not experienced by plaintiff

Defendants argue that the Court should exclude references to complications claimed to result from pelvic mesh products that plaintiff has not experienced, including groin pain, thigh pain, leg pain, and mesh erosion. The Court agrees with plaintiff,

[1] If defendants believe a limiting instruction for this evidence is appropriate, it will be up to them to supply a proposed instruction in a timely fashion.

however, that under Illinois products liability law, whether a product is unreasonably dangerous is evaluated under a test that involves weighing "a broad range of factors," including among others 'the magnitude and probability of the foreseeable risks of harm." *Mikolajczyk v. Ford Motor Co.*, 231 Ill. 2d 516, 555, 901 N.E.2d 329, 352 (2008) (internal quotation marks omitted). *See also, e.g., Lamkin v. Towner*, 138 Ill. 2d 510, 529, 563 N.E.2d 449, 457 (1990) (plaintiff may establish defective design by introducing evidence that product's design proximately caused his injury "and the defendant fails to prove that on balance the benefits of the challenged design outweigh the risk of danger inherent in such designs"); *Calles v. Scripto-Tokai Corp.*, 224 Ill. 2d 247, 255, 864 N.E.2d 249, 255 (2007) ("[A] plaintiff may demonstrate a design defect by presenting evidence that the risk of danger inherent in the challenged design outweighs the benefits of such design."). Contrary to defendants' contention, it defies logic to say that this means that *all* the benefits of the product may be admitted—as defendants plainly intend to do—but only *some* of the risks may be admitted. Plaintiff must, of course, establish that the design of the product caused her particular injury. But the Court declines to prevent her from offering evidence about the *overall* risks and benefits of the product in attempting to prove that a design defect exists—an element distinct from causation. The Court therefore denies defendants' motion *in limine* 12.

15. Certain e-mails

As discussed at the final pretrial conference, the e-mails attached to defendants' motion *in limine* as exhibits T and U are admissible for the non-hearsay purpose of showing notice. The Court also expressed at the conference that defendants' hearsay objection was not well-taken in any event; the e-mails qualify for admission under

Federal Rule of Evidence 803(6).

17. Videos / photos of surgical procedures

Videos or photos of surgical procedures are barred under Federal Rule of Evidence 403, as discussed at the final pretrial conference, unless (as with any other barred evidence) defendants open the door via evidence or argument.

18. Other mesh devices

On defendants' motion 18, the Court adopts the discussion and ruling it made on plaintiff's motion 6.

19. Dr. Chen documents

Evidence and testimony relating to receipt by Dr. Ming Chen (an Ethicon employee) of complaints about TVT products in 2008-09 involves hearsay. Because it postdates the use of the TVT-O product in plaintiff, this evidence does not appear to be relevant to show notice, a non-hearsay use. Plaintiff also contends, however, that this evidence may be admissible to impeach one or more defense experts. This remains to be seen and likely will depend of the testimony offered by defendants from those experts (or others). Plaintiff should bring this issue to the Court's attention at an appropriate time outside the jury's presence before seeking to introduce this evidence.

20. Johnson & Johnson "credo"

Evidence regarding the Johnson & Johnson "credo" is barred as irrelevant and under Federal Rule of Evidence 403.

C. Carryover motions from MDL proceedings

1. Dr. Daniel Elliott

Defendants seek to bar testimony on the following points by plaintiff's expert Dr.

Daniel Elliott:

- the use of surgical procedures (specifically, the Burch procedure) as an alternative to TVT devices;
- other synthetic mesh devices as safer alternatives to the TVT-O;
- the adequacy of defendants' research and testing; and
- complications from TVT devices that plaintiff did not experience.

The Court overrules defendants' first contention. Under Illinois product liability law, a plaintiff may attempt to prove that the design of a product is unreasonably dangerous using the "risk-utility" test. Factors considered when applying this test include:

> (1) the utility of the product to the user and the public;
>
> (2) the likelihood the product will cause injury and the probable severity of the injury;
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> (3) the availability of a substitute product that would meet the same need, more safely;
>
> (4) the ability of the manufacturer to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to be useful;
>
> (5) the user's ability to avoid danger in using the product;
>
> (6) the user's anticipated awareness of the product's dangers, based on general knowledge or suitable warnings or instructions; and
>
> (7) the feasibility of the manufacturer spreading the loss by setting the price of the product or carrying liability insurance.

See, e.g., Calles, 224 Ill. 2d at 264-65, 864 N.E.2d at 260-61.

Defendants argue that other surgical *procedures* are not "substitute *products*" whose utility and safety is relevant under factor 3, and the Court agrees. But the availability of other safe and effective procedures to treat the same condition is relevant and admissible, as plaintiffs contend, to show the utility of the defendants' product (factor 1)—a point not addressed in the other cases upon which defendants rely. The Court also notes that this evidence is admissible to rebut defendants' contention that the TVT-O and similar products are the "gold standard" for treating SUI.

The Court also overrules defendants' contention that Dr. Elliott should not be permitted to testify that other synthetic mesh devices are safer than the TVT-O. The fact that he evidently does not believe that any such devices are safe does not preclude him from ranking them on a comparative basis. This affects only the weight to be given to Dr. Elliott's testimony on this point, not its admissibility. Defendants are, of course, free to cross-examine Dr. Elliott regarding his views of mesh devices generally and regarding any inconsistent testimony or statements he has given.

The Court agrees with defendants' third argument, namely, that Dr. Elliott may not render an opinion regarding the adequacy of defendants' research and testing from a regulatory standpoint; he lacks the relevant expertise on this score. But he may testify (as defendants conceded at the final pretrial conference) regarding whether and why, *as a clinician*, studies and testing conducted by defendants or others are sufficient to impact his opinions regarding the TVT-O or similar devices.

Finally, the Court overrules defendants' argument that Dr. Elliott should be precluded from testifying regarding complications from the TVT-O or similar devices that were not experienced by plaintiff. On this point, the Court incorporates its discussion of

defendants' motion *in limine* 12.

2. Dr. Bruce Rosenzweig

Defendants seek to bar testimony on the following points by plaintiff's expert Dr. Daniel Elliott:

- the use of surgical procedures (specifically, the Burch procedure) as an alternative to TVT devices;
- defendants' compliance with FDA adverse event reporting requirements;
- criticism of the cut of the mesh in the TVT-O device (specifically, mechanical cutting as opposed to laser cutting); and
- complications from TVT devices that plaintiff did not experience.

The first and fourth of these issues are identical to those raised by defendants regarding Dr. Elliott, so the Court adopts its rulings on those issues for Dr. Rosenzweig as well. The second issue is uncontested; plaintiff will not be offering evidence on that point.

This leaves only whether Dr. Rosenzweig may render opinion testimony regarding safety issues arising from the fact that the mesh in the TVT-O is cut mechanically rather than by laser. The MDL court ruled that Dr. Rosenzweig is qualified to opine on this topic. In the present motion, defendants challenge the reliability of his testimony. The Court overrules defendants' objections; they go to the weight to be given to Dr. Rosenzweig's testimony on this point, not its admissibility.

D. Motion to quash subpoena to Dr. David Robinson

The Court denies defendants' motion to quash the trial subpoena to Dr. David

Robinson for the reasons stated at the final pretrial conference.

Date: August 6, 2017

MATTHEW F. KENNELLY
United States District Judge